

BASIC SCIENCE

Standardized bench test evaluation of coronary stents: Biomechanical characteristics

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Abstract

Objectives: The purpose of the study was to develop a standardized and global bench test protocol to evaluate the biomechanical characteristics of the most currently used drug-eluting coronary stents.

Background: The use of coronary stents has contributed to the reduction of cardiovascular mortality but can be associated with specific complications. Improving the biomechanical matching between the stents and the coronary anatomy may reduce these complications.

Methods: We assessed five commercially available drug-eluting stents: the Absorb, Orsiro, Resolute Onyx, Synergy, and Xience Alpine stents. Following stent deployment at nominal pressure in ambient air, radial elastic recoil and foreshortening were measured. Flexibility (crimped and deployed stents) and longitudinal and radial resistances were evaluated using a mechanical tester.

Results: Biomechanical characteristics were significantly different for all tested devices (ANOVA, $P < 0.01$). The Synergy, Orsiro, and Xience Alpine stents presented the lowest elastic recoil. The Synergy and Resolute Onyx stents were the most flexible devices. The Xience Alpine and Absorb stents had the highest longitudinal and radial resistances.

Conclusions: Drug-eluting coronary stents used in current clinical practice have very different biomechanical characteristics, which should be taken into consideration to select the most appropriate device for each clinical situation.

KEYWORDS

bench test, biomechanical performance, coronary stents

1 | INTRODUCTION

Percutaneous coronary intervention has become the gold standard for treating coronary artery disease and mortality rates have declined over the past decades. Balloon angioplasty has improved the prognosis of patients with acute coronary syndrome,¹ and the introduction of coronary stents has subsequently reduced the occurrence of restenosis and major adverse cardiovascular events.² Compared with the bare metal stents, the first generation of drug-eluting stents (DES) markedly decreased the rates of restenosis³ but were associated with

an increased risk of stent thrombosis.⁴ New-generation DES, optimally combining stent platform, drug and drug release kinetics, have further reduced the occurrence of stent restenosis and thrombosis leading to improved clinical outcomes and patient safety.⁵ Such improvements led the scientific community to recommend their use in all clinical situations involving patients with coronary artery disease and an indication for percutaneous coronary intervention.⁶

Stent restenosis and thrombosis are less frequent with the new-generation DES but are still considered major complications.^{7,8} Each stent is associated with specific biomechanical characteristics^{9,10} that may be related to definite benefits and/or complications.^{11,12} Stent deformation or damage induced by specific angioplasty procedures may contribute to restenosis.^{13,14} To date, the perfect stent does not

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exist. Some authors hypothesize that improved biomechanical matching between the stent characteristics and the coronary anatomy may decrease the complications related to coronary stent implantation.¹⁵ However, no systematic comparison of the characteristics of the new-generation stents has been performed and available data are limited to first-generation devices^{9,16} and few isolated biomechanical parameters.^{13,17}

In this context, we conducted an independent, standardized, and global bench test evaluation of some of the most currently used coronary stents in order to compare their characteristics.

2 | MATERIAL AND METHODS

2.1 | Drug-eluting stents

Most of the latest-generation DES were evaluated in this study, including: Absorb GT1 3.0/23 mm (Abbott Vascular, Chicago, Illinois, USA), Orsiro 3.0/22 mm (Biotronik, Berlin, Germany), Resolute Onyx 3.0/22 mm (Medtronic, Minneapolis, Minnesota, USA), Synergy 3.0/20 mm (Boston Scientific, Marlborough, Massachusetts, USA), and Xience Alpine 3.0/23 mm (Abbott Vascular). For a maximal comparability between stents, we chose a diameter of 3.0 mm and a length close to 20 mm, a standard size in clinical practice. Twelve samples of each stent model were tested: three samples were used for the assessment of elastic recoil and foreshortening, three for flexibility analysis, and six for resistance.

Two additional stents, Optimax (Hexacath, Rueil-Malmaison, France) and Resolute (Medtronic), were tested but finally excluded because they do not release any antiproliferative drug, which limits current indication.

Ultimaster (Terumo, Shibuya, Tokyo, Japan), Cre8 (AlviMedica, Istanbul, Turkey), Coroflex Isar (Braun, Melsungen, Germany), Biomatrix and Biofreedom (Biosensors, Singapore, Singapore) stents could not be obtained from manufacturers for this study, due to refusal or delays to provide the devices.

2.2 | Deployment protocol

Stent deployment was performed at room temperature. No phantom was used around the stents in order to minimize the manipulations after deployment. A video clip of stent deployment is available in Supporting information.

The manipulations were performed by a single trained operator for maximal reproducibility. Stent manipulations were minimized and made with appropriated tools (no skin contact). All devices were inflated with their own balloon at nominal pressure, according to manufacturer's recommendations. Particular attention was paid to progressively inflate the absorb bioresorbable vascular scaffold. Nominal pressure was maintained for 30 seconds.

2.3 | Mechanical analysis

All biomechanical measures were performed in accordance with the ASTM F2081. Elastic recoil and foreshortening were calculated from image analysis, in accordance with ASTM 2079. Images from the

bench and the mechanical tester are available in Supporting information.

2.4 | Elastic recoil and foreshortening

Elastic recoil was defined as the percentage change in stent diameter (mean from 3 measurements: both extremities and middle) assessed immediately after inflation and 2 minutes after deflation. Foreshortening was the percentage change in stent length assessed immediately after inflation and 2 minutes after deflation.

2.5 | Bending stiffness

All compression tests performed to assess bending stiffness and resistance were conducted using a texture analyzer TA.HD.Plus (Texture Technologies, Hamilton, Maryland, USA) with a constant 0.01 mm/s deformation mode. Data were treated with Exponent software.

Bending stiffness was defined according to current standards¹⁸ as the maximum force required to obtain a 2 mm deformation on the middle part of the stent during a constant deformation compression at 0.01 mm/s, while the stent extremities are fixed on two semi cylinders of steel, 14 mm apart.

2.6 | Radial resistance

Radial resistance was evaluated in two consecutive steps, using compression between parallel plates. First, the radial elastic limits were determined by a loading–unloading test. The deformation was incrementally increased by 0.1 mm until the stent diameter did not return to the initial value. The radial resistance elastic limit was defined as the highest radial compressive strength applied without any permanent deformation. The radial elastic deformation limit was defined as the highest radial deformation achieved without any permanent deformation. Then, the radial maximal resistance was defined as the maximal strength necessary to reduce the stent diameter from 3 to 2.5 mm during a constant compression test.

The radial resistance elastic limit and the radial maximal resistance were corrected for stent length.

2.7 | Longitudinal resistance

For the longitudinal tests, the stents were donned on a 2-mm-diameter titanium cylinder. Then, they were crimped on this cylinder by a steel clamp, so that exactly 5 mm of the stent stayed free from constriction. The samples were submitted to longitudinal compression using a hollow steel cylinder with outer and inner diameters of 22 mm and 2.7 mm. This evaluation was performed in two consecutive steps. First, the longitudinal elastic limits were determined by a loading–unloading test. The compression was incrementally increased by 0.1 mm until the stent length did not return to the initial value. The longitudinal resistance elastic limit was defined as the highest longitudinal compressive strength applied without any permanent deformation. The longitudinal elastic deformation limit was defined as the highest longitudinal deformation achieved without any permanent deformation. Then, the longitudinal maximal resistance was defined as

the maximal strength necessary to reduce the stent free length from 5 to 3.75 mm during a constant compression test.

2.8 | Statistical analysis

Continuous variables are presented as means and standard deviations.

A one-way analysis of variance (ANOVA) was used for the comparison of continuous variables in conjunction with Tukey's method for multiple comparisons.

For all comparisons, a *P*-value <0.05 was considered as statistically significant. All analyses were conducted with Prism 7 software (GraphPad Software Inc, La Jolla, California, USA).

3 | RESULTS

Biomechanical characteristics are summarized in Table 1. All characteristics were significantly different between devices by ANOVA (*P* = 0.03 for radial resistance elastic limit and longitudinal deformation elastic limit; *P* < 0.001 for all other biomechanical characteristics).

3.1 | Elastic recoil and foreshortening

Mean elastic recoil ranged from 2.52% (Synergy) to 8.26% (Absorb) (Figure 1). The Orsiro, Synergy, and Xience Alpine stents presented elastic recoils that were similar and significantly lower than for other devices (*P* < 0.001). The Absorb stent had the highest elastic recoil (*P* < 0.001).

Foreshortening was low for all devices and ranged from −0.34% (Synergy) to 1.29% (Absorb) (Table 1). The Synergy stent presented a significantly lower foreshortening than all other devices (*P* < 0.001).

3.2 | Bending stiffness

The stiffness of undeployed balloon-crimped stents ranged from 532 mN (Synergy) to 995 mN (Absorb) (Figure 2). There was no significant difference between the Synergy and the Resolute Onyx stents that were more flexible than the other devices (*P* < 0.001). The Absorb stent was significantly less flexible than all other devices (*P* < 0.001).

The stiffness of deployed stents ranged from 75 mN (Resolute Onyx) to 200 mN (Xience Alpine) (Figure 3). The Orsiro and Absorb stents had intermediate flexibility between the more flexible (Resolute

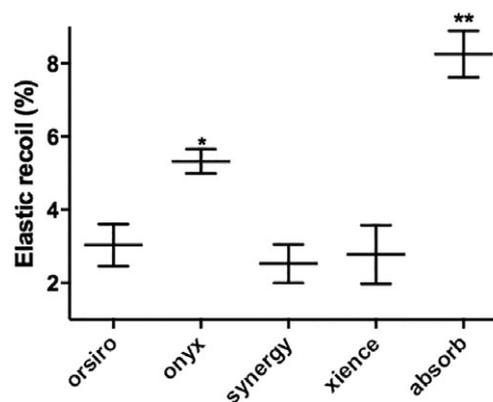


FIGURE 1 Elastic recoil (%). **P* < 0.001 for Resolute Onyx vs Orsiro, Synergy, and Xience alpine***P* < 0.001 for Absorb vs all other devices

Onyx and Synergy) and the more rigid (Xience Alpine) devices (*P* < 0.001).

3.3 | Radial resistance

The radial maximal resistance ranged from 152 mN/mm (Synergy) to 233 mN/mm (Resolute Onyx) (Figure 4). The Orsiro and Synergy stents presented a less important radial resistance than all other devices (*P* < 0.001).

The radial resistance elastic limit ranged from 62 mN/mm (Orsiro) to 104 mN/mm (Absorb) (Table 1). The Orsiro and Synergy stents presented a lower radial resistance elastic limit than the Absorb device (*P* < 0.001). No other significant difference was observed.

The radial deformation elastic limit ranged from 157 μm (Xience Alpine) to 310 μm (Absorb) (Table 1). The Absorb stent presented a higher radial deformation elastic limit than all other devices (*P* < 0.001). No other significant difference was observed.

3.4 | Longitudinal resistance

The longitudinal maximal resistance ranged from 276 mN (Synergy) to 860 mN (Xience Alpine) (Figure 5). The Xience Alpine stent presented a higher longitudinal maximal resistance than all other devices (*P* < 0.001).

The longitudinal resistance elastic limit ranged from 111 mN (Synergy) to 317 mN (Xience Alpine) (Table 1). The Synergy and

TABLE 1 Biomechanical characteristics

	Orsiro N = 12	Resolute onyx N = 12	Synergy N = 12	Xience alpine N = 12	Absorb N = 12
Elastic recoil (%)	3.04 ± 0.75	5.33 ± 0.43	2.52 ± 0.68	2.78 ± 1.03	8.26 ± 0.82
Foreshortening (%)	0.72 ± 0.55	0.75 ± 0.64	−0.34 ± 0.35	0.44 ± 0.51	1.29 ± 0.5
Crimped stent stiffness (mN)	835 ± 25	592 ± 44	532 ± 30	752 ± 28	995 ± 91
Deployed stent stiffness (mN)	135 ± 6	75 ± 5	82 ± 5	200 ± 14	103 ± 4
Radial resistance (mN/mm)	167 ± 14	233 ± 5	152 ± 11	222 ± 14	211 ± 15
Radial resistance elastic limit (mN/mm)	62 ± 16	90 ± 5	64 ± 1	83 ± 6	104 ± 16
Radial deformation elastic limit (μm)	176 ± 25	190 ± 10	173 ± 12	157 ± 35	310 ± 36
Longitudinal resistance (mN)	524 ± 46	415 ± 64	276 ± 87	860 ± 90	559 ± 87
Longitudinal resistance elastic limit (mN)	203 ± 29	131 ± 8	111 ± 8	317 ± 59	243 ± 32
Longitudinal deformation elastic limit (μm)	120 ± 36	193 ± 40	107 ± 23	140 ± 17	237 ± 38

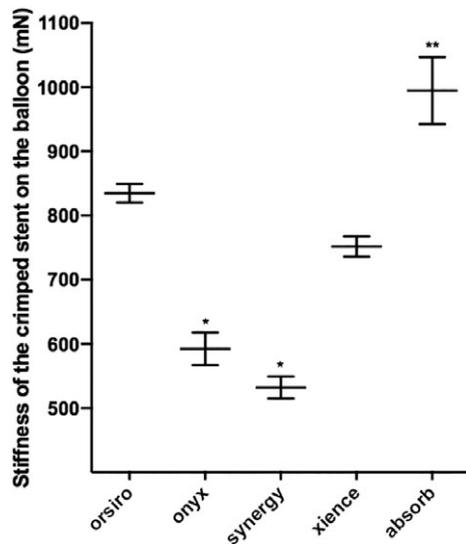


FIGURE 2 Stiffness of the stent crimped on the balloon (mN). * $P < 0.001$ for resolute Onyx and Synergy vs Orsiro and Xience Alpine. ** $P < 0.01$ for Absorb vs all other devices

Resolute Onyx stents presented a lower longitudinal resistance elastic limit than the Xience Alpine device ($P < 0.001$).

The longitudinal deformation elastic limit ranged from 107 μm (Synergy) to 237 μm (Absorb) (Table 1). The Absorb stent presented a significantly higher longitudinal deformation elastic limit than the Xience Alpine, Orsiro, and Synergy devices ($P < 0.001$).

4 | DISCUSSION

Our study highlighted a significant variability in the biomechanical performances of the currently used DES. However, none of the evaluated

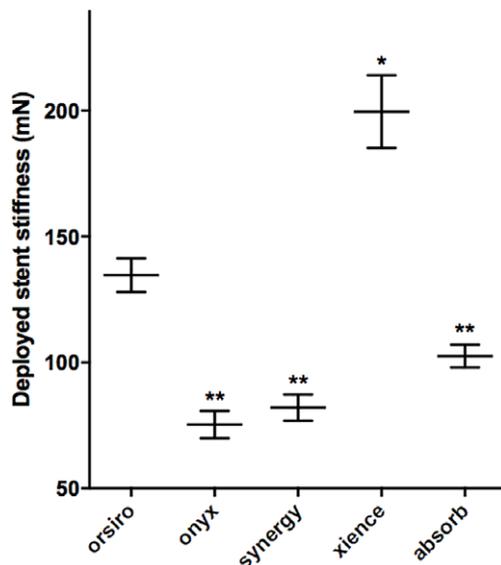


FIGURE 3 Deployed stent stiffness (mN). * $P < 0.001$ for Orsiro and Xience Alpine vs all other devices. ** $P < 0.001$ for Synergy vs Orsiro and Xience Alpine; *** $P < 0.001$ for Absorb vs Orsiro, resolute Onyx, and Xience Alpine

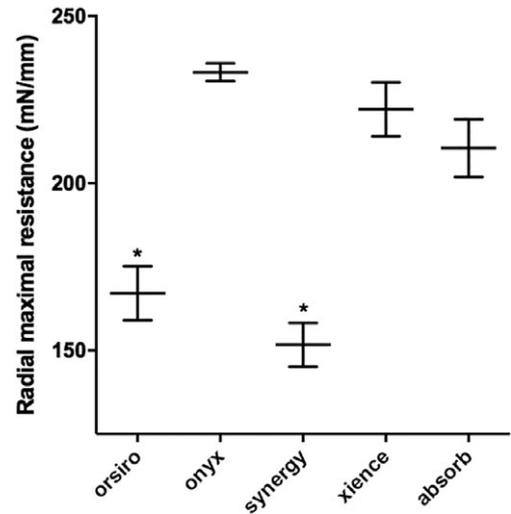


FIGURE 4 Radial maximal resistance (mN/mm). * $P < 0.001$ for Orsiro and Synergy vs Absorb, resolute Onyx, and Xience Alpine

stents exhibited all the ideal biomechanical characteristics, which was already a weakness of older generations of devices.^{9,19}

Our results are in accordance with those of the few studies that assessed similar DES. Kim et al. evaluated the biomechanical characteristics of the Xience-V (Abbott Vascular) stent, which is comparable to the Xience Alpine device, despite some geometrical differences in strut design (longer cell length and taller nonlinear links).⁹ The foreshortening and the flexibility of both devices were comparable. A slight difference was observed in the elastic recoil (2.52% for Xience Alpine vs 4.35% for Xience-V), that is a probable consequence of the evolution in stent design and/or the difference in experimental conditions (room temperature in our study vs 37.5°C in Kim et al.'s). Our results are also in accordance with those of Barragan et al.,²⁰ even though different protocols were used. In that study, the Multilink-8 (Abbott Vascular) stent (similar in design to Xience Alpine) presented a

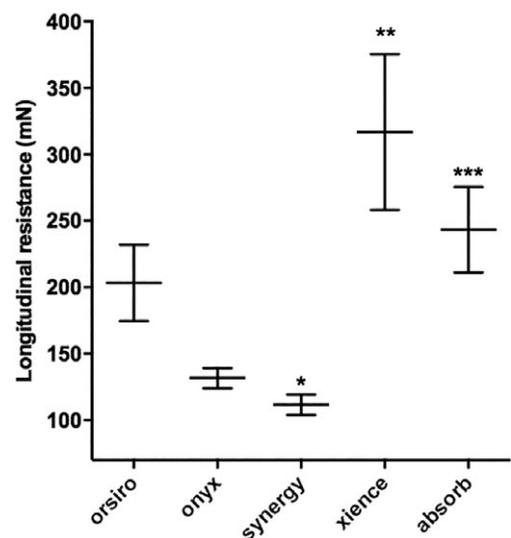


FIGURE 5 Longitudinal maximal resistance (mN). * $P < 0.001$ for Synergy vs Orsiro, Xience Alpine, and Absorb, ** $P < 0.001$ for Xience Alpine vs all other devices; *** $P < 0.001$ for Absorb vs resolute Onyx, Xience Alpine, and Synergy

higher longitudinal resistance than the Orsiro stent and the Promus Element (Boston Scientific) system (similar to Synergy) in line with our grading of these devices. Such observation validates the great reproducibility of each stent biomechanical performances, independently of the protocol that apply.

On the other hand, the biomechanical properties of coronary stents have improved over the past decades. In their comparative study of coronary stents, Barragan et al.²¹ reported an elastic recoil as high as 16.5%, whereas the maximum observed in our study for a series of contemporary stents was 5.4% (8.6% including the no-longer commercialized Absorb stent). New-generation stents have also become more flexible than in the past^{9,16} with values of binding stiffness as low as 532 mN (crimped Synergy stent) or 72 mN (deployed Resolute Onyx stent).

On the other hand, the elastic properties of coronary stents have been underexplored. Our work showed that currently used stents presented slight but significant differences regarding elastic limits, suggesting limited clinical relevance for these parameters. Radial and longitudinal permanent deformations could be induced by low constraints in all stents, mostly below 0.3 mm. Such deformations may be corrected by postdilatation and do not represent a major weakness.

Our results confirmed that the bioresorbable Absorb stent has a very different biomechanical profile compared with the metallic stents, including increased elastic recoil, foreshortening and crimped stiffness. On other hand, the Absorb stent presented a higher elastic tolerance to deformation than the metallic devices with similar elastic tolerance to strength, suggesting a better reversibility of deformation.

This global and standardized bench test evaluation of currently used stents provides important information that may help improving the selection of stents for a better matching with the coronary anatomy. Based on our results, we suggest the choice of a Xience Alpine stent for coronary lesions presenting a high risk of recoil or requiring deep intubation because this stent perform well in compression tests. The Synergy and Resolute Onyx devices may be used preferentially in small vessels, especially if tortuosity is important, because they have high flexibility and low elastic recoil. In large and noncalcified vessels, the Orsiro stent may be a good choice.

4.1 | Study limitations

Although we carefully followed manufacturer's instructions for stents handling and deployment, *in vitro* testing may not fully account for *in vivo* stent behavior. Our results should be confirmed by additional studies, but they support the need for standardized protocols to assess the biomechanical parameters of coronary stents in bench-test evaluations.

5 | CONCLUSION

The currently implanted DES present very different biomechanical characteristics and none of them have an ideal profile suitable for all clinical situations.

Beyond device indication, we believe that the stent elastic recoil is the most important parameter to consider in all clinical situations,

especially for implantation in large vessels. The stent radial and longitudinal resistances are important characteristics to take into consideration when the lesions are prone to recoil (eg, ostial lesions). Finally, flexibility is an essential parameter to treat tortuous and small vessels.

These suggestions do not take into account national recommendations or reimbursement conditions and should be confronted to clinical results.

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DISCLOSURE STATEMENT

The authors have no conflicts of interest to declare.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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